

THE DRAWINGS

Please approve the accompanying replacement drawings. Reference number 333 for the biohazard warnings has been added to Fig. 2. In Fig. 5, reference number 332 is replaced with 330A.

REMARKS

In the present application, the drawings were objected to.

The abstract was objected to.

Claim 16 was rejected under 35 U.S.C. § 112, and claims 1-16 were rejected under 35 U.S.C. § 103. Reexamination, reconsideration, and allowance are respectfully requested.

Entry of the amendments is respectfully requested. No new matter issues are raised by the amendments. Support for the amendments to the specification is evident. With regard to the amendments to the claims, reference to an "insertion region" and a "pouch region" can be found at page 3, lines 11-15.

Objections To The Drawings and Specification

The drawings were objected to because character 332 was used twice and failure to show biohazard warning 331 and printing 335. It is respectfully submitted that the amendments to the specification and the changes to the drawing obviates these objections. In particular, the specification has been clarified with regard to the use of character 332. In both places where character 332 is used it is now referred to as the flood coating.

With regard to the objection that the drawings do not show biohazard warning 333, it has been added to Fig. 2. With regard to the objection the drawings do not show printing 335, use of "335" in the specification was in error, and that has been changed to 333.

It was noted by applicant that reference number 332 was used twice: once for the flood coating (see page 5, line 16) and for an opposed surface of the laminate (page 6, line 3). The second appearance of 332 has been changed to 330A in the specification and in Fig. 5.

The abstract has been amended as requested by the examiner to remove the word "comprised."

It is believed that the amendments to the specification and drawings obviate the objections raised in the office action.

Rejection Under 35 U.S.C. § 112

Claim 16 was rejected under 35 U.S.C. § 112, second paragraph for indefiniteness on the basis that it is not clear how claim 16 further limits claim 4 or 15. This rejection is respectfully traversed.

Claim 16 is a product-by-process claim. Such claims crossing statutory classes are clearly permissible and are not indefinite. See 37 C.F.R. § 1075(b)(2) which specifically deals with claims that cross statutory classes. The rule says they should be treated as independent

claims. MPEP § 2173.05(b) specifically states that use of a product-by-process claim is proper. There is nothing indefinite about claim 16. A person of ordinary skill in the art would know what is within the scope of the claim.

Accordingly, removal of this rejection is respectfully requested.

Rejection Under 35 U.S.C. § 103

All the claims were rejected under 35 U.S.C. § 103 as being obvious over Strong et al., U.S. Patent No. 5,150,971 in view of Palazzolo, U.S. Patent No. 5,918,983. This rejection is respectfully traversed.

The present invention is directed to shipping devices suitable for biohazard specimens, such as fecal specimens. There was need for envelopes for shipping biohazardous specimens where if an envelope is torn or inadvertently opened, thereby providing a biohazardous risk, a biohazard symbol became visible. The present invention solves this need.

For example, as specified in claim 1, a sealable envelope suitable for shipping biohazardous material has an insertion region and a pouch region. The envelope is formed from three layers, an outer layer where mailing information is printed, an inner layer having a printable surface facing the outer layer, and a middle layer between the inner and outer layers. A biohazard warning is printed on the printable surface of the inner layer in the pouch region. Alternatively, as specified in claim 14 the biohazard warning can be printed on the surface of the inner layer that faces away from the outer layer where that surface is protected by a second polymeric layer.

It is submitted that even if the references cited are combined, no *prima facie* case of obviousness is made. In particular, Strong merely describes a conventional specimen mailing device. Palazzolo is directed to a different problem than solved by applicant, and because of that, when combined with Strong, does not yield what is claimed. In particular, Palazzolo is directed to detecting tampering of a security envelope. One feature provided by Palazzolo to detect tampering is to provide an insertion region of the envelope with a frangible header 30 having indicia thereon in an inside surface. In use, as shown by Fig. 5, the header 30 is folded over to seal the insertion region, with the header 30 being on the outside.

So what do we get if we combine Palazzolo with Strong? What we get is an envelope where the insertion region has indicia on the inside surface of the outer layer. This certainly does not solve the problem solved by applicant. This does not provide an indicia that the pouch region has been damaged and biohazardous material, such as a fecal specimen, may be exposed.

The combination of Strong and Palazzolo yields indicia in the insertion region, not the pouch region, and the indicia printed on the outer layer, not an inner layer.

Having the indicia on the outer layer as taught by Palazzolo is unacceptable for applicants' purposes. It would yield too many false warnings. In applicants' invention, as specified in claim 1, two layers in the pouch region need to be penetrated before there is a warning. In Palazzolo's envelope, penetration of just the outer layer 30 in the insertion region yields a warning of tampering. If that were the case in applicants' envelope, there would be warnings when there still at least two layers protecting the envelope contents and the pouch region was not compromised, i.e. an undesirable false warning.

Thus, the combined references do not solve the problem solved by applicants, nor yield what applicants are claiming. Accordingly, it is respectfully submitted that the rejection under 35 U.S.C. § 103 should be withdrawn.

SHELDON MAK ROSE & ANDERSON
100 E. Corson Street, Third Floor
Pasadena, California 91103
(626) 796-4000

Respectfully submitted,

By


Jeffrey G. Sheldon
Reg. No. 27,953